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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/183,824	10/30/98	RAJU T	P1097R1

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	14

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/183,824	Raju
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

☒ Responsive to communication(s) filed on 12/26/2000 and 7/24/2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-44* is/are pending in the application.

Of the above, claim(s) 1-9, 17-35, 37, 39-41, 43 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10-16, 36, 38, 42, 44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

1. Claims 10-16,36,38,42,44 are under consideration. The response filed 12/26/2000 has been entered.

2. The IDS filed 7/24/2000 has been received and considered.

RESPONSE TO APPLICANTS ARGUMENTS

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10-14,38,42,44 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al.

Regarding the term "containing" (as recited in claim 1 upon which claim 10 depends), said term is considered to be equivalent in scope to comprising (eg. open language). Wright et al. teach a composition comprising a human IgG1 antibody wherein said antibody has at least one Ig CH2 domain "containing" G-2 (eg. G-2 plus two additional Manα1) wherein said antibody is free of G2, G1, G0 or G-1 oligosaccharides (see Figure 1 and abstract). Wright et al. teach a composition containing said antibody and a pharmaceutically acceptable carrier (eg. tissue culture media, see page 1090). The claimed article of manufacture is said composition in a test tube. The recitation of an intended use carries no patentable weight in the article of manufacture claim.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth

in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 10-16,36,38,42,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. in view of Paulson et al. and prior art disclosed in the specification (page 16).

Regarding the term "containing" (as recited in claim 1 upon which claim 10 depends), said term is considered to be equivalent in scope to comprising (eg. open language). Wright et al. teach a composition comprising a human IgG1 antibody wherein said antibody has at least one Ig CH2 domain "containing" G-2 (eg. G-2 plus two additional Manα1) wherein said antibody is free of G2, G1, G0 or G-1 oligosaccharides (see Figure 1 and abstract). Wright et al. teach a composition containing said antibody and a pharmaceutically acceptable carrier (eg. tissue culture media, see page 1090). The claimed article of manufacture is said composition in a test tube. The recitation of an intended use carries no patentable weight in the article of manufacture claim. Wright et al. do not teach the antibodies disclosed in claims 15,16. Paulson et al. teach that proteins with altered glycosylation patterns are useful for a variety of purposes including diagnostic and research purposes (see column 3). The specification discloses that a variety of therapeutically useful antiCD20 antibodies were known in the art (see cited references, specification, page 16). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Wright et al. teach a composition comprising a human IgG1 antibody wherein said antibody has at least one Ig CH2 domain "containing" G-2 (eg. G-2 plus two additional Manα1) wherein said antibody is free of G2, G1, G0 or G-1 oligosaccharides and methods of making such antibodies, while the specification discloses that a variety of therapeutically useful antiCD20 antibodies were known in the art. One of ordinary skill in the art would have been motivated to do the aforementioned to have created altered oligosaccharide versions of known therapeutically useful antibodies such as antiCD20 antibodies in order to assess the role of oligosaccharide function in the therapeutic effect seen when said antibody was administered. in addition, Paulson et al. teach that proteins with altered glycosylation patterns are useful for a variety of purposes including diagnostic and

research purposes (see column 3). The G-2 containing antibody would be administered in the form of a pharmaceutical composition which would be prepared as an article of manufacture (eg. said composition in a container).

7. No claim is allowed.

8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7/24/2000 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(I). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose

telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 | 600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644